K100437

510(k) Summary

JAN 12 2012

1. Submitter Information

Company name	Bestgen Biotech Corpration
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Date prepared	Feb. 1st, 2010

2. Name of Device

Trade name	AP-1000 and AP-1000multi Blood Glucose Monitoring System
Common name	Blood Glucose Monitoring System
	Blood Glucose Test Strips
Classification name	Class II devices, 21 CFR Section 862.1345, Glucose Test System
	Class I devices, 21 CFR Section 862.1660, Quality Control Material
Product Code:	CGA, NBW, JJX

3. Predicate Device

Trade name	AP-1000 Blood Glucose Monitoring System
Common name	Blood Glucose Monitoring System
	Blood Glucose Test Strip
Classification name	Class II devices
	21 CFR Section 862.1345, Glucose Test System
510(k) Number	K090389

4. Device Description

The AP-1000 Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1000 test strips and MAJOR control solution with the AP-1000 Blood Glucose Monitoring System.

The AP-1000multi Blood Glucose Monitoring System consists of three main products: the meter, test strip, and control solutions. These products have been designed, tested, and proven to work together as a system accurate blood glucose test results. Use only AP-1000multi test strips and MAJOR control solution with the AP-1000multi Blood Glucose Monitoring System.

5. Intended Use

5.1 AP-1000 Blood Glucose Monitoring System

The AP-1000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. The AP-1000 Blood Glucose Monitoring Systems is intended to be used by a single person and should not be shared. The AP-1000 Blood Glucose Monitoring Systems is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Meter. AP-1000 Meter is intended to be used by a single person and should not be shared. AP-1000 Meter is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-1000 Blood Glucose Test Strips must be used the AP-1000 Blood Glucose Meter. AP-1000 Blood Glucose Test Strips are intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

5.2 AP-1000multi Blood Glucose Monitoring System

The AP-1000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). The AP-1000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system is only used with single-use, auto-disabling lancing device. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). AP-1000multi Blood Glucose Test Strips must be used with the AP-1000multi Meter. AP-1000multi Meter is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in

fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). AP-1000multi Blood Glucose Test Strips must be used with the AP-1000multi Meter. AP-1000multi Blood Glucose Test Strips are intended for testing outside the body (in vitro diagnostic use) and are intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

6. Comparison to Predicate Device

The AP-1000/AP-1000multi Blood Glucose Monitoring System (k100437) has equivalent technological characteristics as the predicate AP-1000 Blood Glucose Monitoring System (K090389). The two devices have same trade name, because of the new added AST function of k100437 device that is based k090389 device to re-test. There are no any changes between the two devices.

7. Performance Studies

The performance of the AP-1000/AP-1000multi Blood Glucose Monitoring System was studied in the laboratory and in clinical settings by healthcare professionals and lay users. The studies demonstrated that the above blood glucose monitoring system is suitable for its intended use.

8. Conclusion

The AP-1000/AP-1000multi Blood Glucose Monitoring System demonstrates satisfactory performance and is suitable for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Bestgen Biotech Corporation
c/o Steven Shen
Quality Assurance Manager
7F., No. 186, Jian 1st Road, Jhonghe City
Taipei County, Taiwan, 23511

JAN 12 2012

Re: k100437
Trade/Device Name: AP-1000 Blood Glucose Monitoring System
AP-1000multi Blood Glucose Monitoring System
Regulation Number: 21 CFR §862.1345
Regulation Name: Blood Glucose Test System
Regulatory Class: Class II
Product Code: NBW, CGA
Dated: December 23, 2011
Received: January 6, 2012

Dear Mr. Shen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: k100437

Device Name: AP-1000 Blood Glucose Monitoring System

Indications for Use:

The AP-1000 Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. The AP-1000 Blood Glucose Monitoring Systems is intended to be used by a single person and should not be shared. The AP-1000 Blood Glucose Monitoring Systems is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-1000 Blood Glucose Test Strips must be used with the AP-1000 Meter. AP-1000 Meter is intended to be used by a single person and should not be shared. AP-1000 Meter is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000 Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh) for self testing by persons with diabetes. AP-1000 Blood Glucose Test Strips must be used the AP-1000 Blood Glucose Meter. AP-1000 Blood Glucose Test Strips are intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as aid to monitor the effectiveness of diabetes control. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use_____ And/Or Over the Counter Use___V___

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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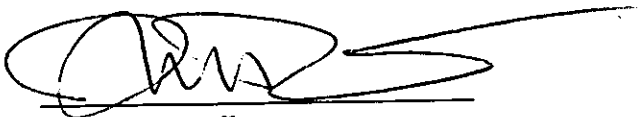
Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k100437

Indications for Use

510(k) Number: k100437

Device Name: AP-1000mutli Blood Glucose Monitoring System

Indications for Use:

The AP-1000multi Blood Glucose Monitoring System is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). The AP-1000multi Blood Glucose Monitoring Systems is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. This system is only used with single-use, auto-disabling lancing device. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000multi Meter is intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). AP-1000multi Blood Glucose Test Strips must be used with the AP-1000multi Meter. AP-1000multi Meter is intended for testing outside the body (in vitro diagnostic use) and is intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

The AP-1000multi Blood Glucose Test Strips are intended for use in the quantitative measurement of glucose in fresh capillary whole blood from the finger and from the alternative sites (palm, forearm, upper arm, calf, and thigh). AP-1000multi Blood Glucose Test Strips must be used with the AP-1000multi Meter. AP-1000multi Blood Glucose Test Strips are intended for testing outside the body (in vitro diagnostic use) and are intended for multi-patient use in professional healthcare settings as an aid to monitor the effectiveness of diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Prescription Use V And/Or Over the Counter Use V

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
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Evaluation and Safety

510(k) k100437